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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,383	06/26/2006	Kyu Hyun Lee	5804900032	3667

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EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,383	LEE ET AL.	
	Examiner	Art Unit	
	KELAGINAMANE T. HIRIYANNA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *2,7,8,13,14,16-20,24 and 25* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *2, 7, 8, 13, 14, 16-20, 24 and 25* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on *11/17/2010* has been entered

Applicant's response filed on *11/17/2010* in response to office action mailed on 01/21/2010 has been acknowledged.

Claims 7, 18, 19, 24 and 25 are amended.

Claims 1, 3-6, 9-12, 15, and 21-23 are cancelled.

Claims 2, 7, 8, 13, 14, 16-20, 24 and 25 are pending and are examined in this office action.

Applicants are required to follow Amendment Practice under revised 37 CFR §1.121. The fax phone numbers for the organization where this application or proceeding is assigned is ***571-273-8300.*** *Applicant's arguments and declarations filed with the response of* 01/21/2010 are fully considered for this office action.

Withdrawn: Claims 1 is rejected under 35 U.S.C. 112, second paragraph, for the reasons of record as set forth in the office action mailed on 01/21/2010 is withdrawn in view of Applicant's cancellation of cited claim.

Withdrawn: Claims *1-8, 13-21, 24, and 25* rejection under 35 U.S.C. 112, first paragraph for the reasons of record as set forth in the office action mailed on 01/21/2010 is withdrawn in view of Applicant's amendments and/or cancellation of cited claims.

Withdrawn: *1-8, 13-21, 24, and 25* rejection under 35 USC 103 (a) as being unpatentable over Chang et al (WO 01/19868 A1; art of record) in view of Trieu et.

al (1999, Biochem. Boiphys. Res. Comm. 257: 714-718; art of record) and Kikuchi et al., (2002, Blood 100:3950-3959; art of record) for the reasons of record as set forth in the office action mailed on 01/21/2010 is withdrawn in view of Applicant's amendments and/or cancellation to claims and further in view of a revised rejection below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, *2, 7, 8, 13, 14, 16-17, 19, 20, 24 and 25* is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claim 2: "a nucleotide sequence represented by SEQ ID NO: 1". This is not clear for if it requires all of SEQ ID NO: 1, or if a simple di-nucleotide sequence is required from SEQ ID NO: 1. Hence, the claim is rejected for lack of clarity.

Claim 8: "a nucleotide sequence represented by SEQ ID NO: 2".This is not clear for if it requires all of SEQ ID NO: 2, or if a simple di-nucleotide sequence is required from SEQ ID NO: 2. Hence the claim is rejected for lack of clarity.

Claim 13: without a modifier to indicate where the plasmid is present in such an amount, it is not clear. Is it required to be a laboratory stock, or is it required to be injected at such amounts, or is it required to reach the site of transformation at such an amount? Hence the claim is rejected for lack of clarity.

Claim 14: without a modifier to indicate where the adeno-associated virus or adenovirus is present in such an amount, it is not clear. Is it required to be a laboratory stock, or is it required to be injected at such amounts, or is it required to reach the site of transformation at such an amount? Hence the claim is rejected for lack of clarity.

Claims 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recitation "directly injecting" makes the claim vague

and indefinite because an artisan would not know where to directly inject. Is this injection is to the site of targeted tumor or is it anywhere on the body of the subject. Appropriate amendment is required.

Claim 20: is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter and also for lack of clarity. Is not every administration chemical, in that a chemical is administered, and is not it also physical for being physically administered? Also, how does conjugation using a liposome accomplish administration? Finally, how is the conjugation and method using a receptor and virus used? Applicant should make appropriate amendments to the claim.

Claim 24 recitation of "is adenovirus" has no antecedent basis.

Claims 2, 7, 8, 13, 14, 16-17, 19, 20, 24 and 25 are rejected as they depend from the rejected claim.

Claim Rejections - 35 USC § 112, 4th Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112,/4th Paragraph.:

> If a dependent claim fails to specify a further limitation of the subject matter or include all the limitations of the claim upon which it depends, the dependent claim should be rejected under § 112, 4th Paragraph.

Claim 20: is rejected under 35 U.S.C. 112, fourth paragraph, as it does not further limit the base claim. Is not every administration chemical, in that a chemical is administered, and is not it also physical for being physically administered? Also, how does conjugation using a liposome accomplish administration? Finally, how is the conjugation and method using a receptor and virus used? Applicant should make appropriate amendments to the claim to avoid double patenting warning.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims *2, 7, 8, 13, 14, 16-20, 24 and 25* stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling a method of treating solid tumors by administering and expression of a nucleic acid molecule encoding the human apolipoprotein (a) kringle KIV9-KIV10-KV (LK68) or KV (LK8) wherein said nucleic acid molecule is carried in a plasmid or AAV or an Adenoviral expression and wherein said vector is administered by a direct injection to the site of tumor, does not enable any route or mode of administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

At issue, under the enablement requirement of 35 U.S.C. 112, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970). These factors include, but are not limited to: (1) The breadth of the claims; (2) The nature of the invention; (3) The state of the prior art; (4) The level of one of ordinary skill; (5) The level of predictability in the art; (6) The amount of direction provided by the inventor; (7) The existence of working examples; and (8) The quantity of experimentation needed to make or use the invention based of the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). All of the wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below as to show that one of the ordinary skill in the art have to go through "undue experimentation" in order to practice the invention.

Nature of the invention: The invention relates to gene therapeutic treatment of solid tumors by administering a subject the gene therapy compositions comprising any gene carrier that expresses recombinant human apolipoprotein (a) kringles KIV9-KIV10-KV (LK68) or KV (LK8) in a plasmid or viral vector. The nature of the invention is such that it required undue experimentation by one of skill in the art to practice the invention in its full scope.

Breadth of the claims And Guidance Provided in the Specification: The scope of the invention encompasses a methods of gene-therapy for treating any human or animal solid tumors by administering a recombinant nucleic acid that encodes a human apolipoprotein (a) kringle KIV9-KIV10-KV (LK68) or KV (LK8) in a plasmid or AAV or a Adenoviral "gene carrier" (expression vector) by a (any) parenteral route to subject with said tumor.

The specification only teaches an enabled use of a AAV-viral vector for introducing a recombinant human apolipoprotein (a) kringle KIV9-KIV10-KV (LK68) or KV (LK8) and using a method of administration of direct injection into a (or the site of) solid tumor in a mice in mice that results in inhibition of growth of the transplanted tumor and a decrease in the rate of fatality.

The specification does not disclose any enabled examples of composition of "gene carriers" other than said AAV vector, does not disclose any enabled examples of broadly claimed treatment of any tumor, further does not disclose an enabled method of treating any tumor by any parenteral administration of said gene-therapy compositions as a route of delivery of said composition to the subject.

The Application a filed does not enable any route of administration said compositions of "gene carriers" other than direct injection in to the target solid tumor. Art at the time of instant invention was highly unpredictable regarding such broadly claimed routes of delivery of tumor gene therapeutic compositions to live subjects that includes humans. Hence, it is incumbent upon the Applicant to provide sufficient guidance in the form of enabled examples in the as filed application.

In the absence of representative number of enabled examples in the specification commensurate with the breadth of the claims one of ordinary skill in the art would conclude that the invention is unpredictable and would require undue experimentation to practice the invention in its full scope. The test is whether the number of claimed genus/or species of method of delivery of tumor gene therapeutic composition and etc., as instantly claimed and prior to the reference date or the date of the activity provided an adequate basis for inferring that the invention has generic applicability.

The level of one of ordinary skill in the Art at the Time of Invention: The level of one of ordinary skill in the art at the time of filing of the instant application is high requiring an advanced degree or training in the relevant field. The status of the art at the time of filing was such that said skilled in the art would not have been able to make or use the invention for its fully claimed scope without undue experimentation.

State of the Art, the Predictability of the Art: At about the effective filing date of the present application art is unpredictable with regard methods in vivo of gene transfers for gene therapeutic purposes both viral and non-viral vectors or compositions of cells or other gene carriers. Further the art is still unpredictable regarding enablement of treating any tumors or cancers employing said broadly claimed method of gene transfers. Even the treatment of tumors using gene therapeutic method art still considers it to be highly experimental area of research and it has been difficult to predict the out come of many therapeutic genes and vector systems because of various factors that govern the expression, therapeutic potential of the transduced genes, and the undesirable host immune reactions etc., in vivo (Reviewed in Goncalves et al, Bioessays, 2005, 27: 506-517; art of record). In addition there exists unpredictability in the art regarding method of parenteral administrations of such gene-therapeutic compositions without specific targeting protocols. More often the compositions in general circulation cause immune reactions and end up in excretory or degradation pathways with the target tissue receiving little or none. Hence, it is incumbent upon the Applicant to provide teachings as to each of the broadly claimed methods work. Only direct injection of the tumors with therapeutic compositions is considered to be reasonably successful. Further the art is unpredictable about the degree to which a foreign gene or vector would interfere with cellular genetic

material as observed in treatment of X-SCID patients " These serious adverse events presented as a leukemia-like syndrome were surprising since the risk of insertional oncogenesis was considered to be negligible based on previous trials and on the perceived, though not universally accepted, notion of random retroviral integration" (Goncalves, Bioessays, 2005, 27: 506-517, p. 514, col.2, 1st paragraph). Thus the unpredictability in the art, at the time of instant filing, regarding the methods and consequences of claimed ex vivo and in vivo gene therapies using any "gene carriers" is such that one of ordinary skill in the art finds the claimed invention highly unpredictable and cause undue experimentation to practice the invention in its fully claimed scope.

Amount of experimentation necessary: Because of the lack of working examples, insufficient guidance and direction provided by Applicant, the inherent unpredictability of the art, and the nature of the invention, one of skill in the art would be required to perform a large amount of experimentation to make and/or use the invention in its full scope as claimed by Applicant. Such experimentation would be required to make sufficient number of "gene carriers" delivery including various viral vectors, plasmid constructs expressing appropriate Kringle peptides and deliver them in various modes of broadly claimed parenteral administrations in to a subject and assess their efficacy in delivering the therapeutic gene and its expression in the target tissue namely the solid tumor. Further one of skill in the art will not able to assess that any prevention of tumor occurred by injecting into any muscle in a subject . Still further regarding treatment of a tumor one of ordinary skill has to assess the in vivo effects, both short term and long term, of the different viral vectors or gene carrier cells on the subject health and immunity. Further these claims are not enabled because one of skilled in the art, at the date of filing, would not be able to rely upon the state of the art in order to successfully predict a priori the in vivo effects of claimed gene carriers and efficacy of various delivery routes. Accordingly, in view of the lack of teachings in the art and lack of guidance provided by the specification with regard to an enabled use of sufficient number of gene carriers and delivery methods for preventing or treating a tumor with said compositions as of around the filing date of instant application and for the specific reasons cited above, it would have

required undue experimentation for one of skill in the art to make and use the full scope of the claimed invention. Hence the rejection is maintained.

Response to Applicant's arguments of *11/17/2010*:

The applicant amends the claims to method claims and argues that claims as amended would over come 35 USC 112nd paragraph enablement rejections for the reasons of record as set forth in the office action of *11/17/2010*. Applicant argues that the specification provides support for the enablement of full breadth of the claim of expressing the therapeutic gene in the solid tumors or patients by administering expression vectors via any parenteral route.

The Applicants arguments are however, found not persuasive. Clearly there is no support provided for treating any tumor with said gene expression vectors that were administered by any parenteral route other than direct injection to an experimental transplanted tumor in a mouse. There is no support for injecting a muscle for treating tumor located in different tissues (for example brain tumor). Applicant should provide at the time of filing support in the form of at enabled example that such is done for solid tumors localized in the different parts or tissues of the body of a subject or should provide guidance in the prior art that such a therapy has been successfully carried out. Hence the one of skill, at the time of instant invention would consider that the instantly filed broad claims to gene therapy using viral or plasmid carrier as undue. Hence the rejection is revised as modified above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims *2, 7, 8, 13, 14, 16-20, 24 and 25* are rejected under 35 USC 103 (a) as being unpatentable over Chang et al (WO 01/19868 A1; art of record) in view of Trieu et. al (1999, Biochem. Boiphys. Res. Comm. 257: 714-718; art of record) and Kikuchi et al., (2002, Blood 100:3950-3959; art of record).

The above claims are directed to a method of treating a tumor in a subject comprising directly injecting or intramuscularly injecting to a subject a nucleic acid construct in a plasmid or AAV or a adenovirus harboring anucleic acid molecule encoding a human apolipoprotein kringle KIV9-KIV10-KV (LK68) or KV (LK8).

Regarding claims Chang teaches compositions comprising vectors with nucleotide sequences SEQ ID NO: 1 or 2 encoding human apolipoprotein kringle KIV9-KIV10-KV (LK68) or KV (LK8) (Abstract, p.1, lines 8-17, p.4, lines 27-36 bridging p.5). Chang further teaches that proteins encoded by said sequences as anticancer agents and inhibit angiogenesis (Abstract), p.3, lines 10-37 bridging p.4-5) and they inhibit endothelial cell proliferation, migration and suppress lung carcinoma (p.15, lines 10-35 bridging p.16-20). Chang however does not teach "gene carrier' compositions with said nucleic acids encoding human apolipoprotein kringle KIV9-KIV10-KV (LK68) or KV (LK8) and or a method of treating tumors by administering said nucleic acids into any animal.

Regarding claims Trieu teaches that there is an established link between cancer and Apo(a) (the protein that contains KIV9-KIV10-KV (LK68) or KV (LK8)) levels and a method of treating Lewis lung carcinoma (LL/2) cancer wherein the cancer cells show a delayed growth of tumor and reduced angiogenesis when provided with apo(a) transgene (Abstract and entire article). Regarding claim 6 Trieu teaches providing CHO-K1 cells over expressing truncated human apo(a) transfected using a vector. Trieu further teaches full length recombinant apo(a) causes tumor suppression (p.714, abstract, col.2, 1st paragraph, 3rd paragraph; p.715, col.1 3rd paragraph, col.2, 1st paragraph; p.716, Fig.2). Trieu additionally teaches that a further characterization of structural components of apo(a) responsible for its previously unappreciated anti-tumor effects may provide the basis for novel and effective cancer treatment methods that employ apo(a) fragment or functional analogs of apo(a) as inhibitors of tumor angiogenesis. Trieu however, teaches that his experiments with a truncated six kringle-IV repeats however, did not show the effect as with a full length Apo(a) coding gene.

However at the time of invention Kikuchi teaches tumor therapy with using kringle-4 containing fragments. Kikuchi teaches gene therapy of tumor using Adenovirus vector containing gene encoding NK4 kringles, short Kringle-4 containing fragments (entire article; abstract)

Regarding limitations in claims of specific vectors used for methods of delivering and expressing said nucleic acid sequences in animal cells, prior art at the time of invention inherently and clearly teaches the use of several of the claimed vectors including viral vectors (for example see Kuo et al, 2001, PNAS 98:4605-4610; art of record) for delivering therapeutic genes into animal cells and for treating a solid tumor and metastasis thereof.

Thus it would have been obvious to one of skill in the art to try gene therapeutic approach that would parallel the success of polypeptide therapy using LK8 and LK68 apo(a) protein kringle fragments as taught by Chang and further incorporate the corresponding nucleic acid sequences for Changs peptide in a expression vector construct to carry out gene therapeutic methods as taught by Trieu for a full length apo(a) gene or short kringle coding sequences of the same. Still further use viral vectors described by Kikuchi for the same gene therapy vectors taught by Kuo for treating a solid tumor in an animal subject. One of the skill in the art would have been motivated to use the gene fragment that codes for LK68 and LK8 kringles in specific viral vector/or vector transfected as these gene carriers increase the efficacy of a tumor therapy. One of skill in the art would have an expectation of success of making and using a pharmaceutical composition for gene therapy of tumors using gene coding sequences for kringles KIV9-KIV10-KV (LK68) or KV (LK8) cloned in viral or non-viral vectors as the art at the time of invention teaches that the polypeptide encoded by these sequences efficiently treat tumor and further teaches that full length apo(a) gene therapy or gene therapy using sequences coding for short kringle fragments (NK4) from other kringle domain containing proteins fragments in therapeutic vectors such as Adenovirus vectors are successful and routine. Thus the invention as claimed would have been *prima facie* obvious to one of skill in the art.

Response to Applicant's arguments of *11/17/2010*:

The applicant amends the claims and argues that claims as amended would over come obviousness rejections based on prior art of Chang et al, Trieu et all and Kikuchi et al. Applicant maintains the argument that all the references cited above teach away from the instant invention and only teach failed gene therapy. Still further Applicant maintains there was an unexplained remarkably superior activity of LK8 and LK68 in gene therapeutic method of treating tumors.

The Applicants arguments however found not persuasive because in the first place the art as taught above do not teach away from gene therapy of tumors with sequence encoding kringle domains of Apo(a) protein. Not succeeding in using the gene sequences encoding shorter fragments of kringles of Apo(a) gene as compared to his significant success with the full length Apo(a) gene does not imply that Trieu is teaching away from using shorter fragments of instant invention. Same is true with Kiuchi who clearly teaches using shorter fragments in gene therapy of tumor. Chang reference using protein therapy clearly defines the components or domain that would more successful in cancer therapy. Further, the instant Application does not provide support for any surprising or dramatic effects in cancer therapy over the prior art of Chang's peptide as to be considered as really significant. the Applicant further should note that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art). Applicant still further should note that It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of

the prior art. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Hence the rejection as revised above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 and 8-10, are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 4, 11 and 12 of patent NO:6,743,428 B1 (Application No.: 10/088,548).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably

distinct from the reference claim because the examined claim is either anticipated by, or would have been obvious over, the reference claim.

The subject matter claimed in the instant application is covered by the cited application. The cited claims teach expression vectors (gene carriers) containing nucleic acids coding for KIV9-KIV10-KV (LK68) or KV (LK8). The cited claims of the '3428 broadly claim expression vectors containing nucleic acids coding for KIV9-KIV10-KV (LK68) or KV (LK8). Accordingly, the claimed process in the present application and the cited patent are obvious variants. Therefore, the inventions as claimed are co-extensive.

Response to Applicant's arguments of *11/17/2010*:

Applicant argues that one the presently claimed invention overcomes the obvious ness rejection over Chang, the present double patenting rejection would also overcome the obviousness.

The Applicants arguments are however, found not persuasive. Hence the rejection is maintained.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna Ph.D.*, whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Thursday from 9 AM-7PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach Ph.D.*, may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

/ROBERT M KELLY/

Primary Examiner, Art Unit 1633